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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DELTAGEN, INC.
1031 Bing Street
San Carlos, CA 94070

EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,754	ALLEN ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-26,28-30,32 and 34-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-26,28-30,32 and 34-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a reply to the Paper filed 14 October 2004 in response to the Non-Final Office Action mailed 16 July 2004. Claims 16 and 23 were withdrawn from consideration and claims 24-33 were considered in the 16 July Office Action. Claims 16, 23, 27, 31 and 33 were canceled, claims 24-26 and 28-30 were amended and claims 32-40 were added in the 14 October Paper. Claims 24-26, 28-30, 32 and 34-40 are pending and under consideration.

Response to Amendment

Rejections and objection to claims 16, 23, 27, 31 and 33 is rendered moot by cancellation of the claims.

Claim Objections

Objection to claims 24, 28 and 30 as containing informalities is withdrawn.

Claim Rejections - 35 USC § 101/§112, first paragraph

Claims 24-26, 28-30 and 32 stand rejected and claims 34-40 are rejected under 35 U.S.C. 101 and 112, first paragraph, because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for reasons of record and herein below in the response to arguments.

Claim Rejections - 35 USC § 112

Claim 32 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. It was previously indicated that the disclosure fails to disclose the relevant identifying characteristics of a cell comprising a disruption of an mTMT gene, wherein the disruption results in enhancement of the normal gene products activity. The cell of claim 32 still encompasses a cell comprising enhancement of the normal gene products activity and Applicant has provided no arguments to rebut the Examiners *prima facie* case, therefore, the claim stands rejected as lacking adequate descriptive support.

Rejection of claims 24-26, 28, 29, 30 and 32 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment of the claims such that the transgenic mouse is limited to comprising a null a null endogenous transmembrane tryptase allele.

Rejection of claim 28 under 35 USC §112 second paragraph as indefinite is withdrawn in view of the amendment.

Claim 29 stands rejected under 35 USC §112, second paragraph as indefinite in reciting in step (b), "the pseudopregnant mouse generates". Once a blastocyst has been implanted in a pseudopregnant mouse the mouse is no longer pseudopregnant. The mouse is actually pregnant. Amending step (b) to read, "...wherein the mouse gives birth..." would be remedial.

Response to Arguments

Claim Rejections - 35 USC § 101/§112, first paragraph

Claims 24-26, 28-30, 32 and 34-40 are rejected under 35 U.S.C. 101 and 112, first paragraph, because the claimed invention is not supported by either a specific and substantial credible asserted utility.

In response to the *prima facie* case set forth in the 16 July Office Action, Applicant asserts, "[t]he present invention has a well-established utility since a person of ordinary skill in the art 'would immediately appreciate why' knockout mice are useful. As a general principal, any knockout mouse has the inherent and well-established utility of defining the function and role of the disrupted target gene, regardless of whether the inventor has described any specific phenotypes, characterizations or properties of the knockout mouse" (page 5). Applicant urges, "the knockout mouse has been accepted by the NIH as the premier model for determining gene function, a utility that is specific, substantial and credible" (page 6). In support of this contention, applicant cites various statements from the art expressing enthusiasm for the use of the knockout mouse to determine gene function.

These arguments have been fully considered but are not deemed persuasive. As stated on page 3 of the previous Office Action, a "specific utility" is, "[a] utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention" (emphasis added). Thus, even assuming, *arguendo*, that knockout mice as general class are useful to define the role and function of a disrupted gene, patentable utility requires that the utility either asserted or readily apparent to the skilled artisan be specific to the subject matter claimed. Furthermore, a "substantial utility" is a "utility that defines a 'real world'

use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use are not substantial utilities" (Office Action, page 3).

With regard to "substantial utilities", MPEP 2107.01 states, "the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use and, therefore, do not define 'substantial utilities': (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved...(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility..." In *Brenner, Comr. Pats. v. Manson,* 148 USPQ 689 (US SupCt 1966), the Supreme Court found that there is a distinction between scientific utility, which is evidenced in the articles cited by Applicant, and patentable utility under 35 USC §101. The Court states, "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing...This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something 'useful', or that we are blind to the prospect that what now seems without 'use' may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful completion" (page 696).

Applicant's assertion that the claimed invention can be used to define the function of the gene knocked-out from the mouse is not a substantial utility because it amounts to using the animal as an object of use-testing. Beyond contributing to the fund of scientific knowledge, the only purpose of determining the functional properties of the mTMT gene is to discover a 'real-world' utility for the mouse or the gene. This is not a patentable utility.

Furthermore, one cannot assume that a mouse comprising a disrupted allele is immediately useful to study the function of the disrupted gene. Olsen *et al.* GABA in the Nervous System (2000), 81-96. Editor(s): Martin, David L.; Olsen, Richard W. Lippincott Williams & Wilkins: Philadelphia, PA teaches, "although gene targeting is often useful in delineating the contribution of a given gene product to phenotypic characteristics observed, some gene knockouts lead to embryonic or perinatal lethality, and others lead to no apparent phenotype. This can arise from a lack of any role for the gene in question in regard to the trait studies or from compensation by other gene products. Analysis of the compensation can yield valuable clues to the genetic pathway" (page 82, column 1, emphasis added). Thus, Olsen states what is well-known in the art, which is that the phenotype displayed by a knockout mouse is a conglomeration comprised of phenotypic characteristics that are a direct result of the ablated gene being absent, mTMT in the instant case, and phenotypic characteristics that are the outward manifestation of a myriad of compensatory responses to the absence of the ablated gene. In the instant case, the application describes only a set of phenotypic characteristics with no disclosure of which characteristics are directly related to the functional properties of the ablated allele and which characteristics are secondary, tertiary, *etc.* effects of compensatory mechanisms. Although compensatory responses might reasonably provide information relevant to understanding the function of the ablated gene once the physiological basis for the compensatory response and its relationship to the ablated gene is understood, significant additional research would be required to develop the claimed mouse to the point that the phenotype disclosed can be correlated with the function of the gene in a meaningful way. In other words, using the mouse to determine the functional properties of the gene would require that the skilled artisan first develop the mouse to

the point that the relationship of the phenotype to the function of the gene is understood. Otherwise, the skilled artisan has no way of knowing how the property being assayed relates to mTMT gene function. Thus, even if one were to accept that studying the function of the ablated allele as a patentable utility for a knockout mouse, which it is not, the mouse claimed in the instant case has not yet been developed to the point that it can be used for that purpose.

Next, Applicant argues that the Office has indicated that research tools are clearly patentable. Applicant cites MPEP §2107.1, I and emphasizes the statement, "[m]any research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility..." However, the remainder of that same paragraph reads, as quoted by applicant, "[a]n assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact 'useful' in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as 'research tool', 'intermediate' or 'for research purposes' are not helpful in determining if an applicant has identified a specific and substantial utility for the invention."

Viewed as a whole, this paragraph is clearly an admonition against concluding that an invention lacks utility simply because it can be labeled a research tool. Obviously the converse is also true, and an argument that an invention has patentable utility because it is a 'research tool' is as invalid as arguing that research tools have no patentable utility. Instead, utility must be assessed based on the particulars of the invention and the disclosure, which assessment can be found in the previous Office Action and herein.

Applicant asserts that commercial use and acceptance is an important indication that the utility of an invention has been recognized by one of skill in the art and alleges that orders for the claimed mouse from two large pharmaceutical companies "more than satisfies the practical utility requirement of section 101" (page 8 of the response). This argument has been fully considered but is not deemed persuasive. First, the case law cited by Applicant dose not support this conclusion. Applicant cites *United States Steel Corp. v. Phillips Petroleum Co.* (CA FC) 9 USPQ2d 1461 wherein the court found that correct finding of infringement of otherwise valid claims mandates as a matter of law a finding of utility under 35 USC §101. In that case, the CAFC cites *Raytheon Company v. Roper Corporation*, 220 USPQ 592 (CA FC 1983) wherein the court found, "Correct finding of infringement of otherwise valid claims mandates as matter of law finding of utility under 35 USC 101... proof of such utility is further supported when claims have on their merits been met with commercial success" (page 592). Thus, the Courts have found that commercial success supports proof of utility established by a finding of infringement. This does not support that applicant's assertion that a rejection under 35 USC §101 based on a lack of patentable utility cannot stand in view of purchases by two large pharmaceutical companies.

Furthermore, even if patentable utility could be established based on a showing of commercial success, no such showing has been made in the instant case. MPEP §716.01(c) II states, "[t]he arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding ...commercial success..." (emphasis added).

Next, Applicant alleges that the Examiners contention that there is no evidence that the TMT gene or the cited phenotypes are associated with any disease is analogous to the arguments made by the Patent Office in *In re Brana*. Applicant urges, "[a]s in *Brana*, Applicant has asserted that the claimed invention is useful for a particular practical purpose, an assertion that would be considered credible by a person of ordinary skill in the art...Definitive proof that the phenotypes observed in the null mouse would be the same as those observed in humans is not a prerequisite to satisfying the utility requirement. It is enough that knockout mice are recognized in the art as models for determining gene function" (page 10; emphasis added). These arguments are not persuasive because, as described above, the assertion that the mouse can be used to determine gene function is not a substantial patentable utility. In *Brana*, the Patent Office had asserted that the disclosed utility was not specific because the specification failed to disclose a disease against which the claimed compounds are useful. The Court concluded that the tumor models represented as specific disease against which the claimed compounds were alleged to be effective and, therefore, the disclosed activity supported a specific use. The second basis for the Boards rejection was that use of the claimed compounds to treat tumors was not credible, but the court also found that the disclosed activity supported a credible utility. However, in the instant case, the utility presently being asserted (*i.e.*, to study the function of the ablated gene) does not meet the requirements for substantial utility. In *In re Brana* the court did not address substantial utility. Instead, the requirements for substantial utility were considered by the Supreme Court in *Brenner v. Manson*, which is discussed herein above.

Finally, Applicant argues that the claimed transgenic mice can be used to study gene expression by insertion of a visible marker into the disrupted allele. However, for the same

reasons set forth above regarding utility to study the ablated gene, using the mouse to study expression of a reporter inserted into the gene is not a substantial utility. Viewed through the prism of patent law, as opposed to basic scientific research, studying gene expression is merely use-testing. Although the mouse comprising a reporter gene inserted into a null allele might yield information regarding the expression of the gene, in the world of commerce, which Applicant acknowledges to be the relevant standard (second paragraph on page 8 of the response), the only conceivable use for the information obtained is to establish a "real-world" utility for the mouse itself or for the gene disrupted. This is not a patentable utility.

In summary, the claimed invention lacks patentable utility under 35 USC §101 because the utility asserted in the specification as a model for disease is neither specific nor substantial for the reasons set forth in the previous Office Action and because the alleged "well-established" utilities asserted in the 11 October response are not substantial. Therefore, the claims lack utility under 35 USC §101 and enablement under 35 USC §112, first paragraph.

Claim Rejections - 35 USC § 112

A rejection was previously set forth against claims 24-26, 28-30 and 32 on the grounds that the skilled artisan would not know how to make the full scope of transgenic mice comprising "disruption" in an endogenous mTMT gene, wherein the mouse exhibits the various phenotypes recited in the claims. This rejection was based on the broad scope of "disruption" as defined in the specification as encompassing enhancement of gene function as well as inhibition of mTMT function and the absence of any teachings in the specification with regard to phenotypes associated with enhanced gene function. In response, Applicant has amended most of the claims

such that the mouse is limited to comprising a null endogenous mTMT allele. However, claim 32 still embraces a cell comprising any "disruption" of an endogenous mTMT allele.

Applicant urges that the art cited in the rejection to demonstrate unpredictability of phenotype arising from any given genotypic modification does not apply to the claimed invention because the claimed mouse has been reduced to practice. While this is true insofar as the mouse is limited to comprising a null allele, the cell of the instant claim 32 is not limited to comprising a null allele. There is no disclosure in the application with regard to how to make a mouse embryonic stem cell comprising enhanced mTMT gene function using a targeting vector having the properties recited in claim 30. Therefore, the skilled artisan would not know how to make the full scope of the claimed cell without undue experimentation.

Furthermore, for the reasons provided in the previous Office Action and herein above, the skilled artisan would not know how to use the claimed invention over any scope.

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Note: The following rejection applies to the extent that the prior art discloses the same compositions and/or method embraced by the instant invention and does not evidence a patentable utility for the invention. MPEP 2122 states: "In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but *no utility need be disclosed by the reference. In re Schoenwald*, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992)" (emphasis added).

Claims 24, 29, 30, 32 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong *et al.* (1999) *J. Biol. Chem.* 274:30784-30793 and Smyth *et al.* (1996) *J. Leukocyte Biol.* 60: 555-562 in view of Capecchi (1989) *Trends Genet.* 5: 70-76. All references are already of record.

The claims have been amended such that they are no longer limited to a transgenic mouse having any recited phenotype or a targeting vector capable of providing any particular

phenotype. Thus, mouse of claim 24 embraces any transgenic mouse comprising a null endogenous mTMT allele, wherein the allele comprises the sequence of SEQ ID NO: 1 and the allele comprising exogenous DNA. Likewise, the targeting construct of claim 30 reads on any nucleic acid comprising a first polynucleotide homologous to a first region of an mTMT gene, a second polynucleotide homologous to a second region of an mTMT gene and a gene encoding a selectable marker located between the first polynucleotide sequence and the second polynucleotide sequence.

Wong *et al.* teaches a nucleic acid comprising an mTMT gene sequence, which comprises the instant SEQ ID NO: 1 (see especially Figures 2, 5 and 6 and the captions thereto). Wong *et al.* does not teach that their constructs should be used to generate a knockout mouse or targeting constructs.

Smyth *et al.* teaches granzymes, a family of serine proteases like mTMT, and advocates that the creation of knockout mice deficient in this gene should elucidate their precise role and biological function. Smyth *et al.* thus teach that knockout mice are a good model to study the function of tryptases and thereby provide the motivation to generate knockout mice having a disruption in the mTMT gene, a transmembrane tryptase (see especially the first full paragraph on page 560). Furthermore, Capecchi teaches methods of generating mice deficient in a gene comprising constructing a targeting construct comprising the limitations of the targeting construct of claim 30 (see especially Figure 2 and the caption thereto), providing a mouse embryonic stem cell comprising a disruption created using the targeting construct according to claim 32, introducing the embryonic stem cell into a blastocyst, introducing the blastocyst into a pseudopregnant mouse to generate chimeric progeny mice, selecting chimeric mice to breed to

produce the transgenic mouse and breeding the chimeric mouse according to the method of claim 29 (see especially Figure 2 and the caption thereto and the section entitled "targeted Disruption of the HPRT Gene" beginning on page 72).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wong *et al.* and Capecchi as claimed in the instant claims 29 and 30 to produce a mouse having the characteristics of the instant claim 24 as suggested by Smyth *et al.* The art teaches each of the elements of the targeting construct of claim 30 and the method of producing a knockout mouse of claim 29, and one would be motivated to combine these teachings in view of the teachings from Smyth *et al.* (*Id*). Thus, the claimed invention as a whole would have been obvious to the skilled artisan at the time of filing.

Furthermore, the limitations of dependent claims 34-37 are also disclosed in the cited art and would be obvious to one of ordinary skill for the reasons set forth herein above. Smyth *et al.* teaches that the knockout mice used to elucidate serine protease function should be homozygous for the null allele according to the limitations of claim 35 (see especially the second paragraph on page 560) which are produced from mice that are heterozygous for the null allele according to claim 34. Further, Capecchi teaches the use of the neomycin resistance selectable marker gene according to claims 36 and 37 (see, *e.g.*, Figure 5).

For these reasons, the invention of claims 24, 29, 30, 32 and 34-37, as a whole, would have been obvious to one of ordinary skill in the art at the time of filing and the claims are properly rejected under 35 USC §103.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.
Examiner
Art Unit 1636

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
SUPERVISORY EXAMINER